IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

GINA KOLAR and IVAN KOLAR, individually, and as husband and wife,	)	
Plaintiffs,	)	
-vs-	)	Case No. CIV-20-0047-F
NUVASIVE, INC., a Delaware corporation,	)	
Defendant.	)	

ORDER

Defendant NuVasive, Inc. moves to dismiss this action under Rule 12(b)(6), Fed. R. Civ. P. Doc. no. 8. The moving brief also refers to the pleading standards of Rules 8(a) and 10(b), Fed. R. Civ. P. Plaintiffs filed a response brief, objecting to dismissal. Doc. no. 10. A reply brief was filed. Doc. no. 11. For the reasons stated below, the motion will be denied.

Standards

The inquiry under Rule 12(b)(6) is whether the complaint contains enough facts to state a claim for relief that is plausible on its face. Ridge at Red Hawk, L.L.C. v. Schneider, 493 F.3d 1174, 1177 (10th Cir., 2007), quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 547 (2007). To survive a motion to dismiss, plaintiffs must nudge their claims across the line from conceivable to plausible. *Id*. The mere metaphysical possibility that some plaintiff could prove some set of facts in support of the pleaded claims is insufficient; the complaint must give the court reason to believe plaintiffs have a reasonable likelihood of mustering factual support for these claims. Ridge at Red Hawk, 493 F.3d at 1177.

In conducting its review, the court assumes the truth of plaintiffs' well-pleaded factual allegations and views them in the light most favorable to the plaintiffs. *Id*. Pleadings that are no more than legal conclusions are not entitled to the assumption of truth; while legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. Ashcroft v. Iqbal, 556 U.S.662, 664 (2009). When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief. *Id*. The court will disregard mere "labels and conclusions" and "[t]hreadbare recitals of the elements of a cause of action" to determine if what remains meets the standard of plausibility. Twombly, 550 U.S. at 555; Iqbal, 556 U.S. at 678.

Under Rule 8(a)(2), a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." *And see*, Erickson v. Pardus, 551 U.S. 89, 93 (2007) (Rule 8(a)(2) requires a short and plain statement of the claim which gives the defendant fair notice of what the claim is and the grounds upon which it rests).

Rule 10(b) provides that, "[i]f doing so would promote clarity, each claim founded on a separate transaction or occurrence…must be stated in a separate count…."

The Complaint

The first amended complaint (doc. no. 4, hereafter "the complaint") is brought by plaintiffs Gina Kolar and her husband Ivan Kolar. It alleges as follows.

On November 7, 2017, Gina Kolar underwent lumbar fusion surgery at L4-S1. The doctor who performed the surgery (not a party) used seven components in that procedure, which are identified with some specificity in the complaint. *Id*. at ¶ 4(a) through (g). Two of those components are pedicle screws: NuVasive 6.5 x 45 mm Pedicle Screw, Item No. 13016545; and NuVasive 6.5 x 40 mm Pedicle Screw, Item No. 13016540. "Said components were designed, manufactured,

distributed, sold and/or placed into the stream of commerce by Defendant, NuVasive." *Id*. at ¶ 4.

Due to persistent and severe low back pain, it was discovered, during exploratory surgery on June 12, 2018 (approximately seven months after the fusion surgery), that "Plaintiff's [Gina Kolar's] lumbar fusion failed due to implant failure of Defendant, NuVasive's above listed components, specifically, but not limited to the early/premature fracture of the S1 pedicle screw due to material failure implanted on November 7, 2017." *Id*. at ¶ 5. "Said mechanical failure required removal of the pedicle screw construct from L4-S1." *Id*. "Failure of the pedicle screw system designed and/or manufactured by Defendant, NuVasive caused Plaintiff, Gina Kolar, to suffer severe injuries to mind and body which are permanent and painful." *Id*.

The listed components which were "manufactured, designed and distributed by Defendant, NuVasive and placed in Plaintiff, Gina Kolar, failed and such failure directly caused and/or contributed to Plaintiff sustaining severe and permanent injuries, pain and suffering, disfigurement and medical expenses." *Id*. at ¶ 6.

"Said components were defective in design and/or manufacture," and "[s]aid defects existed when the components left the hands of Defendant[,] making the components unreasonably dangerous beyond the contemplation of the ordinary user." *Id*. NuVasive "is therefore strictly liable to Plaintiff under the doctrine of manufacturers' products liability." *Id*.

NuVasive "breached applicable implied and express warranties, including warranties of merchantability and fitness for a particular purpose." *Id*. at ¶ 7. NuVasive "failed to provide appropriate warnings regarding the potential dangers associated with the use of said components, including warnings regarding the risk of a failure such as was experienced by Plaintiff." *Id*.

"As a direct and proximate result of the defects existing in said components designed, manufactured, distributed, sold and/or placed into the stream of commerce

by the Defendant, Plaintiff suffered severe injuries to mind and body which are permanent and painful." *Id*. at ¶ 8.

"As a further direct and proximate result of the conduct of the Defendant, NuVasive, Plaintiff's spouse, Ivan Kolar, has and will be deprived of his spouse's services, companionship, consortium and support…." *Id*. at ¶ 9.

Defendant's "conduct evidenced an outrageous and willful disregard for the safety of Plaintiff, for which plaintiff will seek…punitive damages. *Id*. at ¶ 10.

Discussion

As an initial matter, defendant argues the complaint should be dismissed in its entirety because it leaves defendant guessing about the nature of the claims. Plaintiffs, in response, argue that a complaint should not be dismissed for failure to identify the legal theory under which it is brought. Moreover, plaintiffs argue that even though the complaint is not required to do so, it identifies several legal theories of recovery which are adequately supported by allegations of fact. The court finds that the complaint is not so general or conclusory that it leaves the defendant guessing about the nature of the claims.

Next, without waiving its first argument, defendant identifies seven types of claims which defendant, if pressed, would interpret the complaint to allege.[1] Defendant argues that each claim fails for various reasons.

Defendant argues that the strict liability design and manufacturing defect claims, as well as the breach of implied warranty of merchantability claim, fail because the complaint does not adequately allege a product defect. The court rejects this argument. The complaint alleges sufficient detail with respect to the defect or defects. Among other things, the complaint alleges that there was a premature,

[1] As identified by the defendant, the complaint appears to allege claims for: 1) strict liability design defect; 2) strict liability manufacturing defect; 3) breach of the implied warranty of merchantability; 4) breach of the implied warranty of fitness for a particular purpose; 5) breach of an express warranty; 6) strict liability failure to warn; and 7) loss of consortium.

mechanical failure of the S1 pedicle screw implanted on November 7, 2017, and it alleges that the failure required removal of the pedicle screw construct from L4-S1. While the complaint alleges that more than just the pedicle screws were defective, the court is sensitive to the imbalance of information (at least as to design issues) which exists at this stage, in a products liability case based on medical devices. In addition, defendant's authorities regarding the specificity with which a defect must be identified are distinguishable. A number of defendant's cases address a complaint that alleges almost no specifics about the nature of the defect. And some of defendant's cases address issues at the summary judgment stage rather than at the motions to dismiss stage.[2]

Next, defendant argues the strict liability design and manufacturing defect claims fail because the complaint does not adequately allege that the defect caused plaintiffs' injuries. The complaint alleges: fusion surgery using seven components designed and manufactured by the defendant; followed by persistent and increasing low back pain; followed by exploratory surgery at which time it was discovered that the components identified in the complaint, including but not limited to the S1 pedicle screw, had failed, requiring removal of the pedicle screw construct. Based on these and other facts, the complaint alleges that the failure of the pedicle screw system designed and/or manufactured by NuVasive caused plaintiff Gina Kolar to suffer severe injuries. Read as a whole, the complaint adequately alleges causation.

Defendant argues the complaint fails to allege facts to support of a variety of other claims, such as breach of the implied warranty of fitness for a particular

[2] Noting that plaintiff alleges a fracture of a screw manufactured by defendants, the court will acknowledge that it would have been helpful for plaintiff to have alleged whether it was a stress fracture or a fatigue fracture. Examination of the mating fracture surfaces (presumably at least one of which would have been removed and would be within plaintiff's control) would tell that tale. But, at least in the circumstances of this case, the court declines, at this stage, to require plaintiff to get that specific. Obviously, at the expert report stage (as will be discussed at the status and scheduling conference) and the summary judgment stage, considerably more specificity will be necessary.

purpose, breach of express warranty, strict liability failure to warn, and loss of consortium. For example, defendant argues the complaint includes no allegations about any representations made to Gina Kolar's surgeon. In response, plaintiff argues that representations made to Gina Kolar's surgeon about the components put into the stream of commerce by NuVasive, would have necessarily included representations which come with a device's FDA 510(k) approval. The complaint does not include these types of allegations. Nevertheless, the court finds that, in the circumstances of this case, the most prudent approach is not to dismiss any specific claims or theories of liability at this stage.

Lastly, defendant argues plaintiffs' claim for punitive damages should be dismissed. It would be premature to now determine the viability of the punitive damages claim, and this argument is rejected. As so often occurs in product liability cases, that issue may well deserve a hard look at the summary judgment stage.

After careful consideration, the court declines to dismiss any claims under Rule 12(b)(6), Rule 8(a)(2) or Rule 10(b).[3]

Conclusion

The motion to dismiss is **DENIED**.

IT IS SO ORDERED this 15th day of April, 2020.

STEPHEN P. FRIOT
UNITED STATES DISTRICT JUDGE

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[3] Rule 10(b) provides no basis for dismissal because additional clarity is not required, and this action does not involve multiple transactions or occurrences.